REMARKS

Following entry of the foregoing amendments, claims 3, 5 to 7, 9, 10, and 12 to 20 will be pending. Claims 3 and 7 have been amended. Support for the amended claims may be found throughout the specification including in the original claims, for example at page 10, lines 14-20. No new matter is added by these amendments.

Rejections Under 35 U.S.C. § 101

The Examiner rejected claims 3, 5 to 7, 9, 10, and 12 to 20 under 35 U.S.C. § 101, because the claimed invention allegedly "lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." Final Action at page 5. The Board of Appeals and Interferences sustained the rejection on the basis that Applicant's assertion that the sequence has use in the isolation, mapping, and functional analysis of genes associated with nitrogen fixation is not a utility set forth in the specification. *Decision on Appeal* 2008-2456 September 26, 2008, at pages 4-5.

Applicant respectfully requests reconsideration in light of the additional evidence and arguments provided.

The specification as filed discloses that BLASTN and BLASTX analyses are well-known and conventional techniques that can be used to obtain information on nucleic acid sequences. *Specification e.g.,* page 93, line 18, to page 94, line 2. The results of a BLASTX sequence analysis provided in TABLE 2 at page 101 of the specification indicates that SEQ ID NO: 1 has significant identity and homology to a putative POL3 protein from *Arabidopsis*, having NCBI accession number AAC98467 (gi:4063760).[1] *See Specification e.g.,* page 93, line 18, to page 94, line 23. An alignment of the translated protein coding sequence of SEQ ID NO: 1 with the protein having NCBI accession number AAC98467 shows significant relationship between the proteins with a score of 132 and an E value of 10^{-29}, as presented in the alignment below and in the Information Statement accompanying this response.

[1] A copy of the NCBI record for this database entry accompanies the Information Statement submitted with this response.

```
Score =  132 bits (331),  Expect = 1e-29
Identities = 58/114 (50%), Positives = 85/114 (74%), Gaps = 0/114 (0%)

Query  17   HLVSKEFVIHSDHQSLKYIRGQSKLTKRHAKWVEYLEQFPYVIKYKKGKTNVVADALSRR  76
            +L  K FVIH+DH+SLK+++GQ KL KRHA+WVE++E F YVIKYKKGK NVVADALS+R
Sbjct  771  YLWPKVFVIHTDHESLKHLKGQQKLNKRHARWVEFIETFAYVIKYKKGKDNVVADALSQR  830

Query  77   HTLFCSLGAQILGFDNIRDLYALDEHFSPIYESCGKKAQDGFYLAEGYLFKEGK  130
            +TL  +L  +++GF+ I+++Y  D  F  +Y++C K A   ++  + +LF E +
Sbjct  831  YTLLSTLNVKLMGFEQIKEVYETDHDFQEVYKACEKFASGRYFRQDKFLFYENR  884
```

Furthermore, a confirmatory BLASTX analysis comparing SEQ ID NO: 1 with the non-redundant protein database (nr), a copy of which accompanies this response, confirms that the protein sequence encoded by SEQ ID NO: 1 has highly significant correlations (E values in the range of 10^{-30}) with sequences encoding proteins having polymerase activity. *See, e.g.,* the Information Statement submitted herewith.

In *In re Fisher*, the Federal Circuit reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner v. Manson*, 383 U.S. at 534-35, 1966) (emphasis in original). The Court noted that since *Brenner* "our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide *one* identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371. First, the Court indicated that, to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is

that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

In view of the foregoing, a skilled artisan, at the time of the invention and in possession of Applicant's specification, would recognize that the nucleotide sequence of SEQ ID NO.: 1 encoded a DNA polymerase POL3-like protein, or a fragment thereof, based upon the sequence analysis. Thus, based upon the sequence set forth in SEQ ID NO:1 and the protein sequence it encodes, the nucleic acid provided for in SEQ ID NO:1 can be employed to, among other things, obtain related POL3-like proteins. Alternatively, the polypeptide encoded by SEQ ID NO: 1 can be used to raise antibodies to the POL3-like protein it encodes. Such antibodies find use in the localization, detection, or quantitation of any DNA polymerase sharing the epitope to which the antibody is directed. In other words, SEQ ID NO: 1 has utilities specific to it and not generally applicable to any nucleic acid. Therefore, a skilled artisan in possession of the specification would recognize that the specification, by teaching the sequence has homology to a putative POL3 protein, discloses specific, substantial, and credible utilities for the claimed invention that provide an immediate benefit to the public. In other words, the claimed invention meets the utility test set forth in *In re Fisher*. Thus, Applicant respectfully requests that the Examiner withdraw the rejection of claims 3, 5 to 7, 9, 10, and 12 to 20 under 35 U.S.C. § 101.

Rejections Under 35 U.S.C. § 112 first paragraph (Enablement)

A. The Claimed Invention is Enabled Because it has Utility

The Examiner rejected claims 3, 5 to 7, 9, 10, and 12 to 20 under 35 U.S.C. § 112, first paragraph, because, allegedly, "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility... one skilled in the art clearly would not know how to use the claimed invention." Office Action at page 13. Applicant respectfully disagrees with the rejection, and submits that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101. In other words, Applicant respectfully submits that, since the claimed invention has at least one specific, substantial, and

credible utility, the rejection of claims 3, 5 to 7, 9, 10, and 12 to 20 with respect to the enablement requirement of 35 U.S.C. § 112, first paragraph, must be withdrawn.

B. Claims 3, 5 to 7, 9, and 10 are Enabled

The Examiner rejected claims 3, 5 to 7, 9, and 10 on the basis that the claims set forth "transformed plant cells and transgenic plants that have a construct which contains instant SEQ ID NO: 1 or its complement as 'an exogenous promoter region'...." Office Action at page 8.

Applicant respectfully requests reconsideration of the rejection in light of the amendments to the claims and the arguments set forth below. Independent claims 3 and 7 have been amended to recite that the cell and plant comprise, among other thing, "a structural nucleic acid molecule that comprises SEQ ID NO: 1 or the complement thereof, which encodes a protein or peptide."

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection.

C. Claims 12-20 are Enabled

The Examiner rejects claim 12 to 20 under 35 U.S.C. § 112, first paragraph, for lack of enablement on the basis that the specification teaches that the disclosed SEQ ID NO: 1 may comprise regulatory elements, may comprise genes encoding polypeptides or fragments thereof, or may comprise introns. See the Office Action at pages 15 and 16.

Applicant respectfully requests reconsideration of the rejection in light of the arguments set forth below.

It is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. V. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991). "[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to ... enable such a person to make and use the invention without undue experimentation." *Falko-Gunter Falkner v. Inglis,* 448 F.3d 1357, 1388 (Fed. Cir. 2006).

In the instant case the Examiner admits the specification indicates that SEQ ID NO: 1 has homology to a POL3 enzyme. Office Action at page 16. Moreover, Applicant confirms that homology in the pair-wise BLAST analysis of the peptide encoded by SEQ ID NO: 1 and the protein disclosed in NCBI Accession Number AAC98467 (gi:4063760) in the analysis provided in the accompanying Information Statement. A skilled artisan in possession of Applicant's disclosure would recognize that, because one could identify the regions of homology between POL3 and the polypeptide encoded by the nucleic acid sequence set forth in SEQ ID NO: 1, Applicant's sequence can be employed in its capacity as encoding a POL3-like protein or fragment thereof as described above. Thus, the enablement requirement is met because the specification enables at least one mode of making and using the invention.

Rejections Under 35 U.S.C. § 112 first paragraph (Written Description)

Applicant respectfully notes that the Board of Appeals and Interferences reversed the written description rejection.[2]

Rejections Under 35 U.S.C. § 102(b)

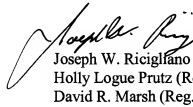
Applicant notes that the rejections under 35 U.S.C. § 102(b) were withdrawn by the Examiner in the Advisory Action mailed Feb 16, 2007.

[2] Applicant notes that the Examiner confirmed the rejection under 35 U.S.C. § 112 first paragraph for written description was withdrawn in the Advisory Action mailed Feb 16, 2007.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5000 should any additional information be necessary for allowance.

Respectfully submitted,



Joseph W. Ricigliano (Reg. No. 48, 511)
Holly Logue Prutz (Reg. No. 47,755)
David R. Marsh (Reg. No. 41,408)

Date: November 21, 2008

ARNOLD & PORTER LLP
Attn: IP Docketing
555 12th Street, N.W.
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile